K083103
page 1 of 1

510(k) Summary

FEB 2 6 2009

Sponsor: AcryMed, Inc.
9560 SW Nimbus Avenue
Beaverton, OR 97008

Contact Person: Dr. Bruce L. Gibbins; (503)-624-9830 ext 301

Device Name AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B

Common Name: Amorphous Hydrogel Gel Wound Dressing

Classification Product Code: FRO

Classification Advisory Panel: General and Plastic Surgery

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Silver Antimicrobial Wound Gel (AcryMed, Inc. Portland OR)
AcryDerm Silver Antimicrobial OTC Wound Gel (AcryMed, Inc. Portland OR)

Description of Device: AcryDerm Antimicrobial Silver Gel Model #B is a repeat use, amorphous hydrogel containing antimicrobial silver for use in the management of wounds.

Intended use of the Device: Under the supervision of a healthcare professional, AcryDerm Silver Antimicrobial Wound Gel Model #B is indicated for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Technological Characteristics: The AcryDerm Antimicrobial Silver Gel Wound Dressings incorporate proprietary stabilized silver salt to facilitate the action of antimicrobial ionic silver in the dressing and wound environment. The gel possesses both moisture donating and moisture sequestering action depending on the moisture level in the wound.

Testing: the new products meets or exceeds safety and biocompatibility assurance guidelines as provided in the guidance of Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*) and the NIH Publication 99-4494. The products meet or exceed the USP <25> Preservative Assurance Testing requirements for a repeat use product.

Manufacturing: The new antimicrobial gel product will be manufactured according to the product specifications and in accordance with good manufacturing practices to ensure the device is safe and effective for their intended uses.

Performance Standards: No performance standards are prescribed for the new product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AcryMed, Inc.
% Bruce Gibbins, Ph.D
Chief Technical Officer
9560 SW Nimbus Avenue
Beaverton, Oregon 97008

FEB 2 6 2009

Re: K083103
Trade/Device Name: AcryDerm Antimicrobial Silver Gel Model #B,
OTC: AcryDerm Wound Gel Model #B
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 20, 2009
Received: February 17, 2009

Dear Dr. Gibbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083103

Device Name: AcryDerm Antimicrobial Silver Gel Model #B

Indications for Use: Under the supervision of a healthcare professional, AcryDerm Silver Antimicrobial Wound Gel Model #B is indicated for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

2/26/2009

Indications for Use

510(k) Number (if known): K083103

Device Name: OTC: AcryDerm Wound Gel Model #B

Over the Counter Use: OTC: AcryDerm Wound Gel Model #B is indicated for the management of minor abrasions, cuts, lacerations and scalds.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) 2/26/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083103